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Request for grant of a patent

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1	Your reference	SPG/P36067
2	Patent application number	**9904232.7** 25 FEB 1999
3	Full name, address and postcode of the applicant	JNA Limited Whitland Abbey Whitland Carmarthenshire SA34 OLG
	Patents ADP number	5878186001
	State of incorporation	England and Wales
4	Title of the invention	Optical Device
5	Name of agent	Harrison Goddard Foote
	Address for service	Belmont House 20 Wood Lane Headingley Leeds LS6 2AE
	Patents ADP number	14571001

6	Priority applications	Country	Priority App No	Date of Filing

Patents Form 1/77

7	Parent application (eg Divisional)	Earlier Application No	Date of Filing
8	Statement of Inventorship Needed?	Yes	
9	Number of sheets for any of the following (not counting copies of same document) Continuation sheets of this form Description Claims Abstract Drawings	 8 1 7	
10	Number of other documents attached Priority documents Translations of priority documents P7/77 P9/77 P10/77 Other documents		
11	I/We request the grant of a patent on the basis of this application. Signature S.P. Gilholm Date 24 Feb 1999		
12	Name and daytime telephone number of person to contact in the United Kingdom	Steve Gilholm ~~+44 113 2258350~~	

OPTICAL DEVICE

This invention relates to an optical device for monitoring or measuring the arterial oxygen saturation with motion artefact suppression.

Monitors are available which use non-invasive optical techniques to measure the arterial oxygen saturation in patients. As is well known in the art, these instruments suffer interference due to patient movement, motion artefact.

For example, it is known, that in order to measure blood oxygen saturation, it is necessary to provide a device which passes light through biological tissue, such as the human finger, and to monitor the transmitted or reflected output signal from a photodetector of this device continuously. Such devices are described, inter alia, in International Patent Application No WO94/03102. Movement of the subject leads to a change in the length of the path of the light through the biological tissue and hence to a variation in the intensity of light received by the photodetector. This renders the device incapable of distinguishing between changes in received light intensity caused by variations in light absorption by the component being monitored (eg oxygen in the blood), and changes in received light intensity caused by variations in the light pathlength due to movement of the subject.

The problem is common to all optical monitoring devices and can render these devices inoperative for long periods of time. The problem is particularly severe in critical health care applications, were continuous monitoring is essential.

We have now devised an optical measuring or monitoring device which is able to monitor or measure the arterial blood oxygen saturation non-invasively and to suppress the effects of motion artefact.

Melanin is present in increasing concentrations from fair through brown to black skin. The peak of its absorption spectrum is at 500nm decreasing almost linearly

with increasing wavelength. Melanin is present in the epidermis, thus, in very high concentrations as is the case in black skin, it can mask the absorption of haemoglobin in the dermis. Even in brown skin, the absorption by melanin is superimposed on that of haemoglobin so that any algorithm which uses the shape of the absorption spectrum in order to produce SO_2 value needs to compensate for this fact.

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In accordance with this invention, there is provided a sensor device which comprises light source means for emitting a light beam, optionally of a plurality of at least three different wavelengths, photodetector means for receiving the light beam after passing through or being reflected within living tissue and arranged to provide signals corresponding to the intensities of the respective wavelengths received by the photodetector means the arrangement being such that the signal levels corresponding to the different wavelengths bear a predetermined relationship with each other, and signal processing means for processing the actual output signals from the photodetectors to cancel out variations due to motion artefact and to provide an output representing a parameter to be measured or monitored and substantially unaffected by motion artefact.

The sensor of the invention may use a spectral wavelength of from 526 to 586 nm.

A particular advantage of the sensor of the invention is that it only enables a user to compare "slopes" on a graph and the use of a range of different wavelengths allows

for a more accurate determination without an increase in costs. In a preferred embodiment of the invention 3 or more different wavelengths are used, the optimum number of wavelengths is 5 or 6.

The sensor device of the invention is generally an optical measuring or monitoring device.

The sensor may be attached to the chest or abdomen of an infant. The tip of the sensor may incorporate a mirror and is provided with an optical fibre light transmitting cable such that the fibre cable lies flat on the surface of the skin. White light (20 to 50W quartz halogen light bulb) is preferred and is transmitted along an optical fibre to the skin where multiple scattering occurs as photons interact with cellular and subcellular particles. Light can be absorbed by the haemoglobin present in the blood flowing in the tissue below the sensor before being scattered back along receiving optical fibres. The scattered light can be transmitted along a plurality eg in the preferred embodiment 6 separate fibres to 6 photodetectors via narrow-band optical filters all in the range 500 to 600nm (green/yellow visible light) and especially between 526 and 586. Generally, the number of detectors should be the same as the number of transmitting fibres. The sensor may optionally be heated above normal body temperature, to eg 40°C and up to 42°C for short periods the temperature may even reach 44°C. Alternatively, a single fibre of from 50 to 150nm in diameter may be used with one to three white LEDs.

According to a further feature of the invention we provide a "hand held" sensor ~~device as hereinbefore described.~~

In particular, in the "hand held" sensor of the invention the optical fibre transmitting cable(s) may be replaced by a light emitting diode (LED) which significantly reduces the complexity of the sensor.

Before use, the sensor is normalised against darkness and a standard white surface, and the signal from each photodiode is measured to obtain the overall dark and "white balance" figures. Signal processing includes averaging for a period between 10 milliseconds to 10 seconds, subtracting the white balance signal, and taking a logarithm to produce a transmittance at each wavelength.

In the preferred embodiments, the use of 6 wavelengths gives the technique a considerable advantage over the pulse oximetry method which uses the minimum number of wavelengths necessary to obtain the information required. The use of more wavelengths in our method gives the technique stability against spurious disturbances at a particular wavelength, enables flexibility in the algorithm to cope with factors such as skin colour. Nevertheless, the sensor of the invention can utilise either oximetry or pulsed oximetry.

Averaging of the signal over a second or more also removes motion artefacts. It is also the case that the technique operates in the visible wavelength range. Thus, although the penetration of light into tissue is much less, the influence of poor contact with the tissue may also be considerably less thus reducing movement artefact. It is important to emphasis that our technique does not measure pulsatility as in the case in pulse oximetry.

SO_2 is the ratio of the oxyhaemoglobin (HbO_2) concentration to the total concentration of haemoglobin expressed as a percentage.

$$SO_2 = \frac{[HbO_2] \times 100}{[HbO_2] + [Hb]}$$

SaO_2 is arterial oxygen saturation